IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	DALTON, James T. et al.	Examiner:	KUMAR, Shailendra
Serial No.:	10/849,039	Group Art Unit:	1621
Filed:	May 20, 2004		
Title:	METABOLITES OF SELECTIVE ANDROGEN RECEPTOR MODULATORS AND METHODS OF USE THEREOF		

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO/SB/08:

1. ☒ listing documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents and/or United States patent application publications are not included in this information disclosure statement; and/or
2. ☐ listing documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Serial No. _____, filed _____ which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
3. ☐ listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement;
4. ☒ listing other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a counterpart foreign application, a copy of which is included with this information disclosure statement.

The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

I) ☐ Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits of the subject Application or a request for continued examination thereof, whichever event occurs last pursuant to of 37 C.F.R §1.97 (b); or

II) ☒ After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;

1. ☐ the undersigned hereby states that each item of information listed on the Form PTO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in §1.56(c) more than three (3) months prior to the filing of this information disclosure statement; or

2. ☒ the undersigned hereby authorizes the Patent Office to charge the fee in the amount of $180.00 under 37 C.F.R §1.17 (p) to Deposit Account 50-3355.

III) ☐ After the period in (I) and (II) but before the payment of the issue fee and,

1. The undersigned hereby states:

a) ☐ that each item of information cited on the form PTO-1449 was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement; or

b) ☐ that no items of information contained in Form PTO-1449 was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and

2. ☐ The undersigned hereby authorizes the Patent Office to charge the Petition fee in the Amount of $180.00 under 37 C.F.R §1.17 (p) to Deposit Account 50-3355.

Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-3355.

Respectfully submitted,

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Attorney/Agent for Applicant(s)
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Dated: November 29, 2006

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	4

Complete if Known	
Application Number	10/849,039
Filing Date	May 20, 2004
First Named Inventor	DALTON, James T.
Art Unit	1621
Examiner Name	KUMAR, Shailendra
Attorney Docket Number	P-5235-US14

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A	09/935,044	08/23/2001	Dalton et al.	
	B	09/935,045	08/23/2001	Dalton et al.	
	C	09/644,970	08/2/2000	Dalton et al.	
	D	6,019,957	02/01/ 2000	Miller, et al.	
	E	6,071,957	06/06/2000	Miller, et al.	
	F	6, 160,011	12/12/2000	Miller, et al.	
	G	4,636,505	01/13/ 1987	Tucker	
	H	4,880,839	11/14/ 1989	Tucker	
	I	4, 465,507	08/14/1984	Konno, et al.	
	J	3,875,229	04/01/1975	Gold	
	K	4, 139,638	02/13/1979	Neri, et al.	
	L	4,191,775	03/04/1980	Glen	
	M	4, 239,776	12/16/1980	Glen, et al.	
	N	4,386,080	05/31/1983	Crossley, et al.	
	O	4, 282,218	08/04/1981	Glen, et al.	
	P	5,609,849	03/11/1997	Kung	
	Q	5, 162,504	11/10/1992	Horoszewicz	
	R	5,656,651	08/12/1997	Sovak, et al.	
	S	6,838,484	01-2005	Steiner, et al	
	T	6,569,896	05-2003	Dalton, et al	
	U	6,998,500	02-2006	Dalton, et al	
	V	7,026,500	04-2006	Dalton, et al	

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	2	of	4

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Application Number	10/849,039
Filing Date	May 20, 2004
First Named Inventor	DALTON, James T.
Art Unit	1621
Examiner Name	KUMAR, Shailendra
Attorney Docket Number	P-5235-US14

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	W	WO98/53826	12/03/1998	Dalton et al.		☐
	X	EP0 100 172	02/08/1984	Tucker		☐
	Y	EP0 040 932	02/12/1981	Crossley et al.		☐
	z	WO95/19770	07/27/1995	Gray		☐
	AA	EP 0253503	12/11/1991	Tucker		☐

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	BB	WO 02 00617	01-03-2002	Bristol Myers Squibb		☐
	CC	WO 01 27622	04-19-2001	Bristol Myers Squibb		☐
	DD	WO 01 28990	04-26-2001	Nobex Corporation		☐
	EE	WO 01 34563	05-17-2001	Nobex Corporation		☐
	FF	WO 98 05962	02-12-198	Panvera Corporation		☐
	GG	EP 000 2892	02-06-1985	Imperial Chemical Indust.		
	HH	JP 52-128329	10-27-1977	Teikoku Hormone Mfg.		
	II	JP 54-63047	12-16-1980	Glen, et al		
	JJ	GB 1360001	03-16-1970	Neri, et al		
	KK	WO 95 19770	07-25-1995	Sepracor Inc.		
	LL	WO 02 016310	02-28-2002	Dalton, et al		
	MM	WO 98 55153	12-10-1998	Dalton, et al		
	NN	WO 03049675	06-19-2003	GTX Inc.		
	OO	WO 03065992	08-14-2003	GTX Inc.		

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 4

Complete if Known	
Application Number	10/849,039
Filing Date	May 20, 2004
First Named Inventor	DALTON, James T.
Art Unit	1621
Examiner Name	KUMAR, Shailendra
Attorney Docket Number	P-5235-US14

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	PP	Howard Tucker and Glynne J. Chesterson, J. Med Chem. 1988, 31, pp. 885-887, "Resolution of the Nonsteroidal Antiandrogen - 4'-Cyano-3-[(4-fluorophenyl)sulfonyl]-2-hydroxy-2-methyl-3'-(trifluoromethyl)-propionanilide and the Determination of the Absolute Configuration of the Active Enantiomer "	☐
	QQ	D. McKillop, et al., "Enantioselective metabolism and pharmacokinetics of Casodex in the male rat", Xenobiotica, 1995, Vol. 25, No. 6, 623-634.	☐
	RR	Leonid Kirkovsky, et al., "[^{125}I]-Radionated Bicalutamide Analogs as Potential Imaging Agents for Prostate Cancer", Poster Presentation MEDI 155, 214th ACS National Meeting, Las Vegas, NV, Sept. 7-11, 1997, Department of Pharmaceutical Sciences, University of Tennessee, Memphis, TN 38163	☐
	SS	David T. Baird and Anna F. Glasier, "Hormonal Contraception - Drug Therapy", The New England Journal of Medicine , May 27, 1993, pp. 1543 - 1549	☐
	TT	F.C. W. Wu, "Male Contraception: Current Status and Future Prospects", Clinical Endocrinology, (1988), 29, pp. 443-465	☐
	UU	Carl Djerassi and S.P. Leibo, "A new look at male contraception", Nature, Vol. 370, pp. 11-12	☐
	VV	World Health Organisation Task Force on Methods for the Regulation of Male Fertility, "Contraceptive efficacy of testosterone-induced azoospermia in normal men", The Lancet, Vol. 336, October 20, 1990, pp. 955-959and 1517-1518	☐
	WW	C. G. Francisco, et al., "Long-acting contraceptive agents: testosterone esters of unsaturated acids", Steroids, January 1990, vol. 55, Butterworths	☐
	XX	John M. Hoberman and Charles E. Yesalis, "The History of Synthetic Testosterone", Scientific American, February 1995, pp. 76-81.	☐
	YY	Leonid Kirkovsky, et al., "Approaches to Irreversible non-steroidal chiral antiandrogens", Department of Pharmaceutical Sciences, University of Tennessee, 47th Southeast/51st Southwest Joint Regional Meeting of the American Chemical Society, Memphis, TN, Nov. 29-Dec. 1, 1995	☐
	ZZ	David J. Handelsman, "Bridging the gender gap in contraception: another hurdle cleared" The Medical Journal of Australia, Vol. 154, February 18, 1996, pp. 230-233.	☐

Examiner Signature		Date Considered	

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Substitute for form 1449B/PTO				Complete if Known	
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				Art Unit	1621
(use as many sheets as necessary)				Examiner Name	KUMAR, Shailendra
Sheet	4	of	4	Attorney Docket Number	P-5235-US14

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	a	Edwards JP, Higuchi RI, Winn DT, Pooley CLF, Caferro TR, Hamann LG, Zhi L, Marschke KB, Goldman ME, and Jones TK. Nonsteroidal androgen receptor agonists based on 4-(trifluoromethyl)-2H-pyrano[3,2-g]quinolin-2-one. Bioorg. Med. Chem. Lett., 9: 1003, 1999.	☐
	b	Zhi L, Tegley CM, Marschke KB, and Jones TK. Switching androgen receptor antagonists to agonists by modifying C-ring substituents on piperidino[3,2-g]quinolone. Bioorg. Med. Chem. Lett., 9: 1009, 1999.	☐
	c	Higuchi RI, Edwards JP, Caferro TR, Ringgenberg JD, Kong JW, Hamann LG, Arienti KL, Marschke KB, Davis RL, Farmer LJ, and Jones TK. 4-Alkyl- and 3,4-diaklyl-1,2,3,4-tetrahydro-8-pyridono[5,6-g]quinolines: potent, nonsteroidal androgen receptor agonists. Bioorg. Med. Chem. Lett., 9:1335,1999.	☐
	d	Hamann LG, Mani NS, Davis RL, Wang XN, Marschke KB, and Jones TK. Discovery of a potent, orally active nonsteroidal androgen receptor agonist: 4-ethyl-1,2,3,4-tetrahydro-6-(trifluoromethyl)-8-pyridono[5,6-g]-quinoline (LG121071). J. Med. Chem., 42: 210, 1999.	☐
	e	Rosen J, Day A, Jones TK, Jones ET, Nadzan AM, and Stein RB. Intracellular receptors and signal transducers and activators of transcription superfamilies: novel targets for small-molecule drug discovery. J. Med. Chem., 38: 4855, 1995.	☐
	f	Dalton JT, Mukherjee A, Zhu Z, Kirkovsky L, and Miller DD. Discovery of Nonsteroidal Androgens. Biochem. Biophys. Res. Commun.,244(1):1-4, 1998.	☐
	g	Edwards JP, West SJ, Pooley CLF, Marschke KB, Farmer LJ, and Jones TK. New nonsteroidal androgen receptor modulators based on 4-(trifluoromethyl)-2-(1H)-Pyrololidino[3,2-g]quinolone. Bioorg. Med. Chem. Lett., 8: 745, 1998.	☐
	h	Eliason, et al "High Throughput Fluorescence Polarazation-Based Screening Assays for the Identification of Novel Nuclear Receptor Ligands." Abstracts of Papers, 223rd ACS National Meeting, Orlando Fla. U.S. 2002	☐
	i	Berger, et al "Concepts and Limitations in the Application of Radiolabeled antiandrogens, estrogens, or androgens as isotropic scanning agents fro the prostate." Invest. Urol. 1975 1391, 10-16	☐
			☐
			☐

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